NQF Process to Receive Comments on Common Formats
Expert Panel Group B Teleconference
Meeting Summary

December 6, 2010

Members present: John R. Clarke, MD; Peter L. Elkin, MD; Arthur Levin, MPH; Scott T. MacLean, MBA; David Classen, MD, (Expert Panel Co-Chair); Henry Johnson, MD, MPH, (Expert Panel Co-Chair); Lori Paine, RN, MS (Expert Panel Member); William Munier, MD, MBA (Expert Panel Liaison Member)

Others present: Peter Goldschmidt, MD, Amy Helwig, MD, John Moquin, Ira Yanowitz (AHRQ).

National Quality Forum (NQF) staff present: Melinda Murphy, RN, MS; Lindsey Tighe, MS.

PURPOSE. The purpose of this meeting was for the group to consider and make recommendations about comments about the Beta version of the Device or Medical/Surgical Supply, including Health Information Technology (HIT) Device, Common Format that had been received through the National Quality Forum (NQF) Common Formats commenting tool and triaged to the Expert Panel. (See attachment)

DISCUSSION AND RECOMMENDATIONS. As lead member of the group charged with considering the comments, Dr. Clarke opened the discussion by asking panel members to first consider the general comments in the context of prior decisions and philosophic underpinnings of the panel's work to date. Through detailed discussion of the type of comments received and careful examination of past determinations, the group affirmed the following:

1. With exception of unsafe conditions, occurrences involving HIT, in general, will implicate the HIT component as a contributing factor rather than a primary cause.
2. Reporting forms, thus event descriptions, should capture the essential information about events and unsafe conditions in a user-friendly way in order to simplify the amount and complexity of data entry by the frontline staff at the point of event occurrence.
   The group was agreed that if forms are complicated and require conduct and capture of complex event analysis, busy staff at the front line will find it impossible to manage the detail and reduced event reporting is a likely outcome.
3. Additional data input and analysis is expected to occur as initial event reports are addressed by managers and as root cause analyses (RCA) are conducted.
4. Most of the comments received recommend collection of additional information that is important and will add value to complete understanding of events, such as can be gained through RCA, though not essential to initial event capture.

The group also discussed the potential value of a reporting form specific to HIT-related events. They noted that those commenting on the HIT-related common format may not have realized that it will be part of the full set of Common Formats. AHRQ staff noted that initial discussions considered separate forms for devices and HIT; however, they recognized the redundancy (about 90 percent) that would occur with separate forms and the dilemma reporters would face in deciding which form should be used for reporting. Both AHRQ staff and the Expert Panel group recognize the tension that exists in trying to balance a reporting structure that allows users to provide initial essential information while acknowledging (and ultimately providing

for) collection of the complex information that will help fully explain occurrences – potentially in a tiered approach.

In considering the comments regarding definition of HIT, AHRQ staff noted that the definition "An HIT device includes hardware or software that is used to electronically create, maintain, analyze, store, receive, or otherwise aid in the diagnosis, cure, mitigation, treatment, or prevention of disease, and that is not an integral part of (1) an implantable device or (2) an item of medical equipment" was agreed upon with the Food and Drug Administration. This is consistent with AHRQ's approach to working with regulatory bodies with interest in the topics covered by the Common Formats.

In considering the level of detail that the Patient Safety Organizations and Network of Safety Databases can accept and address, a group member recommended that provision be made for "screen capture" of HIT-related issues contributing to error to accompany the narrative description of occurrences. In this way, the initial information would be preserved for those analyzing the information at the local level. The issues of potential unfamiliarity with "screen capture" at the front line and incompatibility of reporting vehicle and "screen capture" as well as potential solutions for these were explored.

The group repeatedly expressed appreciation for the value and importance of the detail provided by the comments received. In keeping with the premise that initial reporting forms should contain an essential minimum for event understanding, members suggested that the full content of the comments be considered in developing an initial RCA format focused on HIT. AHRQ staff noted the focus for development has been on the areas where patients are most harmed but that they understand the rationale for the recommendation and will address it.

The group recommends that:

1. The HIT-related Common Format reporting form require as much detail as is needed for initial understanding of the occurrence and that no more detail be added unless it conceptually simplifies data collection.
2. AHRQ should review and improve definitions and instructions in the HIT-related common format using the pertinent comments from the attached list and considering the comments focused on clarification about what HIT is and what it includes.
3. AHRQ should mine the full list of commenter recommendations for content as it develops the planned RCA Common Formats.
4. AHRQ should consider the HIT area of concern in its initial RCA development work as an important opportunity to advance usability and adoption of reporting formats and ultimately to facilitate improvement of the technology.
5. AHRQ should consider a) adding a question to the reporting form to elicit information about whether there was alarm fatigue; e.g., alarm warnings ignored and b) reversing the order of reporting form Questions 20 and 24. (See "Alert fatigue/alarm fatigue" and "Comments on the Reporting Form" on attached list.)
6. AHRQ should add to its instruction for data collection that "screen capture" of HIT-related items perceived as being cause or contributor to an occurrence be captured for local use as an important part of the reporting narrative.

PUBLIC COMMENT. None.

ADJOURN.

Attachment